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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,681	08/05/2003	Steven Gareth Griffiths	H-32310B	8395

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,681	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/355,474.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/5/03*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1. The Preliminary Amendment filed 8/5/03 has been acknowledged and entered. Claims 8-23 are currently pending and under examination.

Specification

2. The disclosure is objected to because of the following informalities:

The specification must be amended at page 4, lines 8-27 to include the sequence identifier number of the sequence disclosed, i.e., SEQ ID NO:1.

On page 1, line 4, the species "*Renibacterium salmoniarun*" should be changed to "*Reninbacterium salmoninarum*".

Appropriate correction is required.

Priority

3. On page 1, first sentence of the specification, the current status of all nonprovisional parent applications referenced should be updated, e.g., 'now U.S. Patent No. 6,627,203' should be added.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 11, 13, 15, 17, 19, 21 and 23 are vague and indefinite because it is unclear whether the adjuvant is co-administered with the dose of the Arthrobacter

species or if it administered at a separate point and time. Clarification and correction is requested.

The Genus/species bacterial names "Arthrobacter" and "Renibacterium salmoninarum" should be italicized in the claims.

Claim Rejections - 35 USC § 112-Scope of Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "a method of inducing an immune response against *Renibacterium salmoninarum* in fish comprising administering an effective immunizing dose of Arthrobacter strain Rsxll to said fish" and "a method of immunizing a fish to a disease caused by *Renibacterium salmoninarum* comprising administering an effective immunizing dose of Arthrobacter strain Rsxll to said fish" does not reasonably provide enablement for any of the methods recited above in which ***any species*** of Arthrobacter is used, nor is it enabled for "a method for preventing the occurrence of bacterial kidney disease in fish comprising administering an effective amount of Arthrobacter strain Rsxll or any Arthrobacter to said fish", "a method for treating bacterial kidney disease in fish comprising administering an effective amount of Arthrobacter strain Rsxll or Arthrobacter to said fish". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are drawn to the use of *any* species of Arthrobacter while the studies performed by Applicant used the specific strain RsxII. It is unclear that any live, non-virulent Arthrobacter strain would be able to produce similar results. The instant specification on the bottom of page 6-page 7 states that Arthrobacter species strain RsxII has been shown to stimulate the immune system of Atlantic salmon as demonstrated by lymphocyte proliferation assays and that direct challenge studies of Atlantic salmon infected at 12-14 weeks by peritoneal injection with the pathogen (*R.salmoninarium*) were protected. During the prosecution of the parent application, 09/355,474, Applicants adequately provided results that demonstrated Arthrobacter strain RsXII could be used as a vaccine to protect against infection with *Renibacterium salmoninarum*. These results are outlined in a published article by the applicants, Griffiths et al. Fish & Shellfish Immunology, 1998, 8:607-619 which does not qualify as prior art. However, the instant specification and original claims never mentioned treating or preventing bacterial kidney disease. The disclosure only provides for methods for protecting against *Renibacterium salmoninarum* and methods of raising an

immune response against *Renibacterium salmoninarum*. Additionally, on page 7, lines 33-36, the specification specifically states that the vaccine is "protective rather than a treatment and therefore reduces the chan[c]es of an infection becoming established...". Accordingly, the specification actually teaches against vaccines and methods of treatment such as recited in claims 20-23. With regard to claims 16-23, the specification and original claims do not provide written description for "A method of treating bacterial kidney disease in fish in need of treatment thereof..." or "A method for preventing the occurrence of bacterial kidney disease in fish". The only methods disclosed and enabled by the instant specification are "methods of inducing an immune response against *Renibacterium salmoninarum*" and "methods for protecting against *Renibacterium salmoninarum*". It is noted that only the specific species, Arthrobacter strain RsxII, is enabled for use in these methods.

The Genus of Arthrobacter comprises species which are very different from one another. During the prosecution of the parent file (09/355,474), Applicants pointed out in the amendment filed 4/9/03 that all of the Arthrobacter species recited in the Koch et al. are very different from strain RsxII. They also argued that Arthrobacter strain HS 29 disclosed in the Mori et al. reference was also very different from strain RsxII. Applicants further argued that the Arthrobacter strain in the Karaskiewicz et al. reference has high metabolic and biogeochemical activity within hydrocarbon transformation which is distinct and different from Arthrobacter strain RsxII. Lastly, strain NEB#688 from the Morgan et al reference was also shown to be distinct and different from the RsxII reference instantly recited. Accordingly, one can see that the

characteristics of Arthrobacter strains are very different. Applicants have only provided a description of a single species of Arthrobacter, strain Rsxll. Results are only provided using this specific strain. The prior art teaches that the properties of Arthrobacter strains vary greatly and it would take undue experimentation for one of ordinary skill in the art to discover another Arthrobacter species/strain which could be effectively used as a vaccine to protect against *Renibacterium salmoninarum* infection in fish. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Claims 8-15 should be limited to use of the Rsxll strain.

Claim Rejections - 35 USC § 112-Written Description

8. Claims 16-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification and original claims do not provide written description for "A method of treating bacterial kidney disease in fish in need of treatment thereof..." or "A method for preventing the occurrence of bacterial kidney disease in fish". Written description is only provided for "methods of inducing an immune response against *Renibacterium salmoninarum*" and "methods for protecting against *Renibacterium salmoninarum*". "Bacterial kidney disease" is only mentioned in the background information on page 1, lines 11-25, of the specification. However, nowhere does the specification teach or suggest that bacterial kidney disease is being treated. Additionally, on page 7, lines 33-36, the specification specifically states that the vaccine is "protective rather than a treatment and therefore reduces the chan[c]es of an infection becoming established...". The original disclosure does not mention "vaccines or methods for treating bacterial kidney disease" or "methods of protecting against/treating bacterial kidney disease". Written description is only provided for "vaccines against *Renibacterium salmoninarum*" and methods of raising an immune response against *Renibacterium salmoninarum*. The recitation of 'methods for treating or preventing the occurrence of bacterial kidney disease in fish" was not recited in the original disclosure. The statement that *Renibacterium salmoninarum* is a causative agent of bacterial onkidney disease in fish on the first page of the specification is not sufficient to provide written description support for "methods of treating or preventing the occurrence of

bacterial kidney disease in fish throught the administration of Arthrobacter".

Accordingly, claims 16-23 contain new matter. Correction is required.

9. No prior art was found.

10. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser 7/19/04
Primary Examiner
Art Unit 1645